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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,683

09/02/2005

Frederic Impellizzeri

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EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

12/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,683	Applicant(s) IMPELLIZZERI, FREDERIC	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-21, 23, 25, 26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21, 23, 25, 26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/10/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21, 23, 25-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite that the openings have a "top diameter . . . and a bottom diameter smaller than said top diameter." The examiner cannot find this in the drawings. Rather, the drawings appear to show a bottom diameter that is larger.

In addition, the term "direct molding" in claim 26 is not found in the originally filed disclosure, which only appears to reference "molding."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21, 23, 25-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (US 6,004,323) in view of Frigg (US 6,206,881) and Estes (US 5,578,034) and Kaute (US 3,596,656).

Park et al. disclose a self-locking osteosynthesis device comprising:
a plate (14) having a plurality of openings formed therein (see FIG. 4B), each of said plurality of openings having a top diameter with a top edge forming a shoulder within said opening (col. 2, ll. 62-67, 4, note: that the specification states that "at least one end" of the nut has a deformable lip, thus, the lip can be formed at both or either ends) and a bottom diameter smaller than said top diameter (due to the presence of the shoulder 4), said plate being formed of a metallic material (col. 5, ll. 10-24); a plurality of inserts (2) respectively fixedly and non-rotationally received in said plurality of openings, each of said plurality of inserts being formed of a biocompatible polymeric material, each insert fixedly engaging the bottom surface of said lip/shoulder at the top of said opening; and a plurality of bone screws (15) respectively received in the hole of said

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plurality of inserts, each insert being fixed relative to said plate when a respective bone screw is being angularly received in said hole of said plurality of inserts.

The plurality of inserts are formed of a thermoplastic polymer (e.g. UHMWPE).

The plate is formed of titanium (col. 5, ll. 21).

The plurality of inserts are mechanically secured respectively in said plurality of openings.

Regarding claim 26, it is noted that the recitation "by direct molding from casting" is a product-by-process recitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Park et al. disclose the claimed invention except for conical openings and tapping bone screw heads having a conical shape; and the inserts engaging and extending above the top surface of said plate.

Frigg et al. disclose tapping bone screw heads having a conical shape and conical threading allowing the bone screws to be angularly received into threaded conical openings to achieve locking even when the bone screw is imperfectly inserted coaxially (see FIG. 1-2, col. 2, lines 1-7 and line 24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device

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of Park et al. with tapping bone screw heads having a conical shape and conical threading allowing the bone screw to be angularly received into threaded conical openings in view of Frigg et al. to achieve locking even when the bone screw is imperfectly inserted coaxially.

Estes shows that it was known that shoulders can be used to keep inserts from backing out (see e.g. FIG. 1, 6, 7), and further that having an insert engage both surfaces of a shoulder aids in keeping the insert from moving too much in either direction. However, Estes shows an insert that is flush with the top surface. Kaute (US 3,596,656) states that the inserts may be flush with the plate, or in the alternative, extend slightly past the top surface plate (col. 2, ll. 70-71). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Park et al. with engaging and extending above the top surface of said plate in view of Estes and Kaute to keep the insert from moving too much in either direction (Estes), and since extending the insert past the top surface is an obvious alternative to keeping the insert flush with the plate (Kaute).

Regarding 21, Park et al. in view of Frigg et al., Estes, and Kaute disclose the claimed invention except for the insert polymer being a polyether-ether-ketone material. It would have been obvious to one having ordinary skill in the art at the time the invention was made make the insert polymer a polyether-ether-ketone material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733